



HPTN Study Operations Report

April 2010

PTN Executive Summary Report
14 April 2010
Enrollment Summary

| Protocol | Site | Date of First Enrollment | Target Number | Total Enrolled | % Target Enrollment | Months of Enrollment | Cumulative Enrollment Per Month | % Enrollment Period |
|-----------------------|--|---------------------------------|----------------------|-----------------------|----------------------------|-----------------------------|--|----------------------------|
| 046 V2 (Mothers) | Uganda – Mulago Hospital | 08Feb2007 | 190 | 190 | 100% | 8.2 | 23.2 | completed |
| | Zimbabwe – Harare/Chitungwiza | 09Mar2007 | 157 | 157 | 100% | 7.8 | 20.1 | completed |
| | Total | | 347 | 347 | 100% | 8.8 | 39.4 | |
| 046 V2 (Infants) | Uganda – Mulago Hospital | 08Feb2007 | 190 | 193 | 102% | 8.2 | 23.5 | completed |
| | Zimbabwe – Harare/Chitungwiza | 09Mar2007 | 157 | 157 | 100% | 7.8 | 20.1 | completed |
| | Total | | 347 | 350 | 101% | 8.8 | 39.8 | |
| 046 V3 (Mothers) | South Africa – Durban – Prince Mshiyeni Hospital | 22Jul2008 | 400 | 408 | 102% | 18 | 22.7 | completed |
| | Tanzania – Dar Es Salaam | 28Jan2009 | 270 | 216 | 80% | 10 | 21.6 | closed |
| | Uganda – Mulago Hospital | 23Jun2008 | 500 | 545 | 109% | 19.2 | 28.4 | completed |
| | Zimbabwe – Harare/Chitungwiza | 14May2008 | 500 | 506 | 101% | 20.5 | 24.7 | completed |
| | Total | | 1670 | 1675 | 100% | 20.5 | 81.7 | |
| 046 V3 (Infants) | South Africa – Durban – Prince Mshiyeni Hospital | 22Jul2008 | 400 | 409 | 102% | 18 | 22.7 | completed |
| | Tanzania – Dar Es Salaam | 28Jan2009 | 270 | 219 | 81% | 10 | 21.9 | closed |
| | Uganda – Mulago Hospital | 23Jun2008 | 500 | 562 | 112% | 19.2 | 29.3 | completed |
| | Zimbabwe – Harare/Chitungwiza | 14May2008 | 500 | 510 | 102% | 20.5 | 24.9 | completed |
| | Total | | 1670 | 1700 | 102% | 20.5 | 82.9 | |
| 052 Run-in (Indexes) | US – Boston – Fenway Community Health Center | 24Oct2005 | 6 | 2 | 33% | 11.5 | 0.2 | closed |
| | Brazil – Porto Alegre | 30Jan2006 | 5 | 5 | 100% | 3.3 | 1.5 | completed |
| | Brazil – Rio de Janeiro | 22Sep2005 | 15 | 15 | 100% | 2.2 | 6.8 | completed |
| | India – Chennai – YRGCare | 10Nov2005 | 10 | 10 | 100% | 1.3 | 7.7 | completed |
| | India – Pune | 01Jul2005 | 10 | 10 | 100% | 2.2 | 4.5 | completed |
| | Malawi – Blantyre – Queen Elizabeth Central | 25Aug2005 | 10 | 10 | 100% | 6.9 | 1.4 | completed |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 12Apr2005 | 10 | 10 | 100% | 1.2 | 8.3 | completed |
| | Thailand – Chiang Mai | 24Jun2005 | 10 | 10 | 100% | 2.3 | 4.3 | completed |
| | Zimbabwe – Harare – Parirenyatwa Hospital | 09Jan2006 | 10 | 10 | 100% | 2.4 | 4.2 | completed |
| | Total | | 86 | 82 | 95% | 18 | 4.6 | |
| 052 Run-in (Partners) | US – Boston – Fenway Community Health Center | 24Oct2005 | 6 | 2 | 33% | 11.5 | 0.2 | closed |
| | Brazil – Porto Alegre | 30Jan2006 | 5 | 5 | 100% | 3.3 | 1.5 | completed |
| | Brazil – Rio de Janeiro | 22Sep2005 | 15 | 15 | 100% | 2.2 | 6.8 | completed |
| | India – Chennai – YRGCare | 10Nov2005 | 10 | 10 | 100% | 1.3 | 7.7 | completed |
| | India – Pune | 01Jul2005 | 10 | 10 | 100% | 2.2 | 4.5 | completed |

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|---------------------------|---|--------------------------|---------------|----------------|---------------------|----------------------|---------------------------------|---------------------|
| | Malawi – Blantyre – Queen Elizabeth Central | 25Aug2005 | 10 | 11 | 110% | 6.9 | 1.6 | completed |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 12Apr2005 | 10 | 10 | 100% | 1.2 | 8.3 | completed |
| | Thailand – Chiang Mai | 24Jun2005 | 10 | 10 | 100% | 2.3 | 4.3 | completed |
| | Zimbabwe – Harare – Parirenyatwa Hospital | 09Jan2006 | 10 | 10 | 100% | 2.4 | 4.2 | completed |
| | Total | | 86 | 83 | 97% | 18 | 4.6 | |
| 052 Full Study (Indexes) | Botswana – Gabarone | 16Apr2009 | 65 | 76 | 117% | 12.1 | 6.3 | 104% |
| | Brazil – Porto Alegre | 26Nov2007 | 93 | 84 | 90% | 29 | 2.9 | 102% |
| | Brazil – Rio de Janeiro | 14Nov2007 | 185 | 169 | 91% | 29.4 | 5.7 | 102% |
| | India – Chennai – YRGCare | 05Jul2007 | 240 | 240 | 100% | 29.8 | 8.1 | completed |
| | India – Pune | 28Jun2007 | 190 | 165 | 87% | 34 | 4.9 | 101% |
| | Kenya – Kisumu | 03Nov2009 | 45 | 56 | 124% | 5.4 | 10.4 | 109% |
| | Malawi – Blantyre – Queen Elizabeth Central | 16Jan2008 | 215 | 219 | 102% | 27.3 | 8 | 102% |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 06Dec2007 | 240 | 241 | 100% | 28.7 | 8.4 | 102% |
| | South Africa – Johannesburg – Witwatersrand | 20May2008 | 55 | 44 | 80% | 23.1 | 1.9 | 102% |
| | South Africa – Soweto | 11Jun2009 | 30 | 47 | 157% | 10.2 | 4.6 | 105% |
| | Thailand – Chiang Mai | 11Oct2007 | 90 | 96 | 107% | 30.1 | 3.2 | completed |
| | Zimbabwe – Harare – Parirenyatwa Hospital | 05Nov2007 | 220 | 227 | 103% | 29.7 | 7.6 | 102% |
| | Total | | 1668 | 1664 | 100% | 34 | 48.9 | |
| 052 Full Study (Partners) | Botswana – Gabarone | 16Apr2009 | 65 | 76 | 117% | 12.1 | 6.3 | 104% |
| | Brazil – Porto Alegre | 26Nov2007 | 93 | 86 | 92% | 29 | 3 | 102% |
| | Brazil – Rio de Janeiro | 14Nov2007 | 185 | 170 | 92% | 29.4 | 5.8 | 102% |
| | India – Chennai – YRGCare | 05Jul2007 | 240 | 240 | 100% | 29.8 | 8.1 | completed |
| | India – Pune | 28Jun2007 | 190 | 165 | 87% | 34 | 4.9 | 101% |
| | Kenya – Kisumu | 05Nov2009 | 45 | 56 | 124% | 5.3 | 10.6 | 110% |
| | Malawi – Blantyre – Queen Elizabeth Central | 16Jan2008 | 215 | 218 | 101% | 27.3 | 8 | 102% |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 06Dec2007 | 240 | 245 | 102% | 28.7 | 8.5 | 102% |
| | South Africa – Johannesburg – Witwatersrand | 20May2008 | 55 | 44 | 80% | 23.1 | 1.9 | 102% |
| | South Africa – Soweto | 11Jun2009 | 30 | 47 | 157% | 10.2 | 4.6 | 105% |
| | Thailand – Chiang Mai | 11Oct2007 | 90 | 97 | 108% | 30.1 | 3.2 | completed |
| | Zimbabwe – Harare – Parirenyatwa Hospital | 05Nov2007 | 220 | 227 | 103% | 29.7 | 7.6 | 102% |
| | Total | | 1668 | 1671 | 100% | 34 | 49.1 | |
| 057 (Mothers) | Brazil – Belo Horizonte | 08Aug2007 | 12 | 8 | 67% | 32.7 | 0.2 | completed |

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|---------------|---|--------------------------|---------------|----------------|---------------------|----------------------|---------------------------------|---------------------|
| | Brazil – Porto Alegre – Conceicao | 15Jun2008 | 8 | 5 | 63% | 22.3 | 0.2 | completed |
| | Brazil – Porto Alegre – Santa Casa | 19Sep2007 | 15 | 13 | 87% | 31.3 | 0.4 | completed |
| | Brazil – Rio de Janeiro | 17Apr2008 | 8 | 7 | 88% | 24.2 | 0.3 | completed |
| | Malawi – Blantyre – Queen Elizabeth Central | 26Dec2006 | 71 | 56 | 79% | 40.2 | 1.4 | completed |
| | Total | | 80 | 89 | 111% | 40.2 | 2.2 | |
| 057 (Infants) | Brazil – Belo Horizonte | 08Aug2007 | 12 | 8 | 67% | 32.7 | 0.2 | completed |
| | Brazil – Porto Alegre – Conceicao | 15Jun2008 | 8 | 5 | 63% | 22.3 | 0.2 | completed |
| | Brazil – Porto Alegre – Santa Casa | 19Sep2007 | 15 | 13 | 87% | 31.3 | 0.4 | completed |
| | Brazil – Rio de Janeiro | 17Apr2008 | 8 | 7 | 88% | 24.2 | 0.3 | completed |
| | Malawi – Blantyre – Queen Elizabeth Central | 27Dec2006 | 71 | 56 | 79% | 40.1 | 1.4 | completed |
| Total | | 80 | 89 | 111% | 40.1 | 2.2 | | |
| 058 | China – Guangxi – Heng County | 24Dec2008 | 400 | 228 | 57% | 15.9 | 14.3 | 43% |
| | China – Xinjiang | 23Dec2008 | 490 | 242 | 49% | 15.9 | 15.2 | 43% |
| | Thailand – Chiang Mai University | 30May2007 | 202 | 202 | 100% | 28.7 | 7 | completed |
| | Total | | 1500 | 672 | 45% | 35 | 19.2 | |
| 061 | US – Atlanta | 26Feb2010 | 201 | 19 | 9% | 1.6 | 11.9 | 15% |
| | US – Boston | 17Jul2009 | 403 | 126 | 31% | 9 | 14 | 51% |
| | US – Decatur | 16Sep2009 | 202 | 112 | 55% | 7 | 16 | 44% |
| | US – Los Angeles | 30Sep2009 | 403 | 142 | 35% | 6.5 | 21.8 | 43% |
| | US – NY – Harlem Prevention Center | 08Jan2010 | 201 | 70 | 35% | 3.2 | 21.9 | 27% |
| | US – NY – New York Blood Center | 01Oct2009 | 202 | 70 | 35% | 6.5 | 10.8 | 43% |
| | US – San Francisco | 13Aug2009 | 403 | 135 | 33% | 8.1 | 16.7 | 48% |
| | US – Washington DC | 28Jul2009 | 403 | 122 | 30% | 8.7 | 14 | 50% |
| Total | | 2418 | 796 | 33% | 9 | 88.4 | | |
| 064 (Women) | US – Atlanta | 22Oct2009 | 200 | 157 | 79% | 5.8 | 27.1 | 95% |
| | US – Baltimore | 05Aug2009 | 200 | 170 | 85% | 8.4 | 20.2 | 137% |
| | US – Chapel Hill | 26May2009 | 200 | 210 | 105% | 8.7 | 24.1 | completed |
| | US – Decatur | 27Aug2009 | 200 | 116 | 58% | 7.7 | 15.1 | 125% |
| | US – NY – Bronx-Lebanon Hospital Center | 16Jun2009 | 200 | 210 | 105% | 8.4 | 25 | completed |
| | US – NY – Harlem Prevention Center | 26Oct2009 | 200 | 119 | 60% | 5.7 | 20.9 | 97% |
| US – Newark | 05Jun2009 | 400 | 395 | 99% | 10.4 | 38 | 171% | |

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|-----------------|---|---------------------------------|----------------------|-----------------------|----------------------------|-----------------------------|--|----------------------------|
| | US – Raleigh | 11Aug2009 | 200 | 210 | 105% | 5.7 | 36.8 | completed |
| | US – Washington DC | 17Jun2009 | 200 | 203 | 102% | 9.8 | 20.7 | completed |
| | Total | | 2000 | 1790 | 90% | 10.8 | 165.7 | |
| 064 (Men) | US – Decatur | 10Mar2010 | 30 | 11 | 37% | 1.2 | 9.2 | |
| | US – NY – Bronx–Lebanon Hospital Center | 30Sep2009 | 30 | 40 | 133% | 6.3 | 6.3 | completed |
| | US – Raleigh | – | 30 | – | – | 0 | – | |
| | US – Washington DC | – | 30 | – | – | 0 | – | |
| | Total | | 120 | 51 | 43% | 6.5 | 7.8 | |

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Retention Summary

| Protocol | Site | Total Enrolled | Expected Visits | Completed Visits | Protocol Expectations | Retention Rate | Protocol Expected Standard |
|-------------------------|--|----------------|-----------------|------------------|-----------------------|----------------|----------------------------|
| 046 V2 (Mothers) | Uganda – Mulago Hospital | 190 | 1140 | 1057 | 1071 | 93% | 94% |
| | Zimbabwe – Harare/Chitungwiza | 157 | 942 | 821 | 885 | 87% | 94% |
| | Total | 347 | 2082 | 1878 | 1956 | 90% | 94% |
| 046 V2 (Infants) | Uganda – Mulago Hospital | 193 | 2123 | 1997 | 2015 | 94% | 95% |
| | Zimbabwe – Harare/Chitungwiza | 157 | 1727 | 1611 | 1639 | 93% | 95% |
| | Total | 350 | 3850 | 3608 | 3654 | 94% | 95% |
| 046 V3 (Mothers) | South Africa – Durban – Prince Mshiyeni Hospital | 408 | 1807 | 1600 | 1738 | 89% | 96% |
| | Tanzania – Dar Es Salaam | 216 | 848 | 781 | 825 | 92% | 97% |
| | Uganda – Mulago Hospital | 545 | 2316 | 2210 | 2232 | 95% | 96% |
| | Zimbabwe – Harare/Chitungwiza | 506 | 2224 | 2083 | 2138 | 94% | 96% |
| | Total | 1675 | 7195 | 6674 | 6934 | 93% | 96% |
| 046 V3 (Infants) | South Africa – Durban – Prince Mshiyeni Hospital | 409 | 3657 | 3402 | 3521 | 93% | 96% |
| | Tanzania – Dar Es Salaam | 219 | 1816 | 1684 | 1761 | 93% | 97% |
| | Uganda – Mulago Hospital | 562 | 4835 | 4698 | 4661 | 97% | 96% |
| | Zimbabwe – Harare/Chitungwiza | 510 | 4521 | 4276 | 4352 | 95% | 96% |
| | Total | 1700 | 14829 | 14060 | 14295 | 95% | 96% |
| 052 Combined (Indexes) | Botswana – Gaborone | 76 | 223 | 217 | 222 | 97% | 99% |
| | Brazil – Porto Alegre | 89 | 635 | 623 | 625 | 98% | 98% |
| | Brazil – Rio de Janeiro | 182 | 1531 | 1496 | 1501 | 98% | 98% |
| | India – Chennai – YRGCare | 250 | 1985 | 1837 | 1949 | 93% | 98% |
| | India – Pune | 175 | 1362 | 1352 | 1335 | 99% | 98% |
| | Kenya – Kisumu | 56 | 81 | 75 | 81 | 93% | 100% |
| | Malawi – Blantyre – Queen Elizabeth Central | 229 | 1333 | 1270 | 1314 | 95% | 99% |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 251 | 1624 | 1527 | 1598 | 94% | 98% |
| | South Africa – Johannesburg – Witwatersrand | 44 | 233 | 224 | 231 | 96% | 99% |
| | South Africa – Soweto | 47 | 91 | 85 | 91 | 93% | 100% |
| | Thailand – Chiang Mai | 106 | 847 | 837 | 829 | 99% | 98% |
| | Zimbabwe – Harare – Parirenyatwa Hospital | 237 | 1392 | 1324 | 1371 | 95% | 98% |
| | Total | 1742 | 11337 | 10867 | 11145 | 96% | 98% |
| 052 Combined (Partners) | Botswana – Gaborone | 76 | 223 | 205 | 222 | 92% | 99% |
| | Brazil – Porto Alegre | 91 | 635 | 605 | 625 | 95% | 98% |

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Retention Summary

| Protocol | Site | Total Enrolled | Expected Visits | Completed Visits | Protocol Expectations | Retention Rate | Protocol Expected Standard |
|---------------|---|----------------|-----------------|------------------|-----------------------|----------------|----------------------------|
| | Brazil – Rio de Janeiro | 183 | 1531 | 1310 | 1501 | 86% | 98% |
| | India – Chennai – YRGCare | 250 | 1985 | 1718 | 1949 | 87% | 98% |
| | India – Pune | 175 | 1362 | 1319 | 1335 | 97% | 98% |
| | Kenya – Kisumu | 56 | 81 | 73 | 81 | 90% | 100% |
| | Malawi – Blantyre – Queen Elizabeth Central | 229 | 1333 | 1132 | 1314 | 85% | 99% |
| | Malawi – Lilongwe – Lilongwe Central Hospital | 255 | 1624 | 1396 | 1598 | 86% | 98% |
| | South Africa – Johannesburg – Witwatersrand | 44 | 233 | 212 | 231 | 91% | 99% |
| | South Africa – Soweto | 47 | 91 | 81 | 91 | 89% | 100% |
| | Thailand – Chiang Mai | 107 | 847 | 774 | 829 | 91% | 98% |
| | Zimbabwe – Harare – Parirenyatwa Hospital | 237 | 1392 | 1203 | 1371 | 86% | 98% |
| | Total | 1750 | 11337 | 10028 | 11145 | 88% | 98% |
| 057 (Mothers) | Brazil – Belo Horizonte | 8 | 48 | 48 | 46 | 100% | 97% |
| | Brazil – Porto Alegre – Conceicao | 5 | 30 | 30 | 29 | 100% | 97% |
| | Brazil – Porto Alegre – Santa Casa | 13 | 78 | 76 | 75 | 97% | 97% |
| | Brazil – Rio de Janeiro | 7 | 42 | 42 | 41 | 100% | 97% |
| | Malawi – Blantyre – Queen Elizabeth Central | 56 | 336 | 325 | 325 | 97% | 97% |
| | Total | 89 | 534 | 521 | 516 | 98% | 97% |
| 057 (Infants) | Brazil – Belo Horizonte | 8 | 56 | 56 | 54 | 100% | 96% |
| | Brazil – Porto Alegre – Conceicao | 5 | 35 | 35 | 34 | 100% | 96% |
| | Brazil – Porto Alegre – Santa Casa | 13 | 91 | 89 | 87 | 98% | 96% |
| | Brazil – Rio de Janeiro | 7 | 49 | 49 | 47 | 100% | 96% |
| | Malawi – Blantyre – Queen Elizabeth Central | 56 | 392 | 376 | 376 | 96% | 96% |
| | Total | 89 | 623 | 605 | 598 | 97% | 96% |
| 058 | China – Guangxi – Heng County | 228 | 165 | 132 | 154 | 80% | 93% |
| | China – Xinjiang | 242 | 226 | 175 | 210 | 77% | 93% |
| | Thailand – Chiang Mai University | 202 | 459 | 404 | 411 | 88% | 90% |
| | Total | 672 | 850 | 711 | 775 | 84% | 91% |

MEMORANDUM

| | |
|--------------|--|
| DATE: | 19 APR 2006 |
| TO: | Study Operations Group |
| FROM: | Deborah Donnell |
| RE: | Summary of HPTN and MTN Enrollment and Recruitment |
| CC: | |

These tables are based on the same data as the protocol specific enrollment and retention reports routinely sent out by SCHARP to each of the protocol teams.

Enrollment Summary

The Enrollment Summary describes the number of participants enrolled in each study based on the data received and entered at SCHARP. The report lists the date of **First Enrollment**, the **Target Number** of participants, and the **Total Number** enrolled to date for each site in each study. The percentage of target already enrolled is:

$$\text{Target Enrollment} = \frac{\text{Total Enrolled}}{\text{Target Number}}$$

As a guide to the sites' progress in enrollment, the percentage **Enrollment Period** elapsed is calculated - this is the elapsed proportion of the accrual period specified in the protocol.

Retention Summary

The Retention Summary is based on study visits. The table reports the number of **Expected Visits** for each site on each protocol - this is a calculation of all visits that should have occurred to date assuming no missed visits or loss to followup. **Completed Visits** are the number of these expected visits that have actually occurred (based on data received and entered at SCHARP). **Protocol Expectations** calculates the number of visits that should have occurred to date assuming the protocol specified acceptable loss to followup rate. Currently the report uses a retention standard of 10% annual loss to followup for HPTN035, HPTN037, and HPTN039 (i.e., Phase IIb and III trials), and 0% for the safety run-in phase of HPTN052.

Retention is simply the proportion of expected visits that have been completed:

$$\text{Retention} = \frac{\text{Completed}}{\text{Expected}}$$

As a guide for performance, the **Protocol Expected Standard** is calculated as the percentage of **Protocol Expected** visits that have occurred:

$$\text{Protocol Expected Standard} = \frac{\text{Protocol Expected}}{\text{Expected}}$$

The network evaluation committee has defined adequate performance as within 90% of the protocol expected standard.

Questions about this report may be directed to Deborah Donnell (deborah@scharp.org; (206) 667-5661).

HPTN Network Laboratory Update April 2010

HPTN 027 (Uganda only)

Specimens for antibody assay are awaiting testing.

HPTN 046

A. General Comments

Version 3.0 dated 26 Sept, 2007

Enrollment at all sites has been stopped.

B. Site Specific

1. Harare - No new updates
2. Kampala - No new updates
3. Durban - No new updates
4. Dar es Salaam - No new updates

Maternal QA shipments from all sites have been received at the Network Lab and are currently being tested.

Lists for infant QA shipments are being compiled

HPTN 052

A. General Comments

The NL is continuing to work on QAing the viral loads from enrollment samples (<1000 copies/mL) as well as the ARV testing. The IQA has requested a change in calculating the percentage CD4s for the FACScout users: Blantyre, Lilongwe and YRGcare.

B. Site Specific

1. Pune/NARI – The site has proposed a new site and new timeline has been submitted to DCLOT. The site is preparing the validation documents for the NL to review.
2. Harare - The site is working on the action plan from the NL November visit. The site is waiting for hepatitis kits to complete screening testing.
3. Chennai - The site is also planning to move part of the laboratory. Pending documentation on the move.
4. Blantyre - The NL is working with the site on some processing issues.
5. Porto Alegre - the site has had a delay in receiving HIV EIA FDA approved kits. The kits were ordered several months ago. This is still pending.
6. Rio sites – The site has been having some difficulty importing the Roche kit for Viral Load. This issue is being raised with Roche international and is being discussed on the cross network Lab Focus Group.
7. Lilongwe – Inventory has not been received for several months. Reminders have been sent to the lab manager.
8. Chiang Mai – No new updates
9. Johannesburg – WITs – No new updates
10. Soweto – No new updates.
11. Botswana – The lab is using the back up laboratory for chemistry.
12. Kenya – No new updates

HPTN 057

A. General Information

A new version of the SSP has been written to include Cohort 4. Lab section has been posted on the HPTN website.

B. Site Specific

1. Blantyre - No outstanding issues. Site is ready to start Cohort 4.
2. Santa Casa. Porto Alegre - No outstanding issues.
3. UFMG. Belo Horizonte -Central lab corrective action plan has many outstanding items.
4. HSE Rio.- No outstanding issues. SOPs have been updated.
5. HNSC. Porto Alegre - No outstanding issues.

HPTN 058

A. Site Specific

1. Thailand - Screening specimens for QA have been received at the Network Lab.
2. China sites.
 - a. Xinjiang Site - No new updates.
 - b. Guangxi - No new updates.
3. An additional site in Vietnam is still being considered.
Network Lab has still not received permission from DAIDS to communicate with the site.

HPTN 061 and 064

General Information

Team protocol trainings for 061 and 064 have been completed. DCLOT has agreed with the Network Lab proposals for rapid HIV testing which allows sites to follow local state regulations.

A. 061 Site Specific

1. Fenway - Protocol Deviation submitted for 2nd Western Blots that were not drawn. NL site assessment visit schedule for March 31st 2010
2. George Washington University - No new updates
3. San Francisco - NL completed site assessment visit on March 12th 2010
4. Harlem - Note to file received for dual enrollments at Harlem..
5. Atlanta - Note to File pending on confirmatory RPR testing that were not done.
6. New York Blood Center - Protocol Deviation submitted for Western blots, viral loads and CD4s that were not done. Note to File for dual enrollment pending.
7. UCLA - NL completed site assessment visit March 11th 2010.

B. 064 Site Specific

1. North Carolina: No new updates.
2. New Jersey: NL completed a site visit on February 12, 2010.
3. Washington DC: No new updates.
4. Bronx: NL completed a site visit on February 11, 2010.
5. Baltimore: No new updates. .
6. Harlem: NL completed a site visit on February 09, 2010.
7. Atlanta: No new updates.

QC update

The following sites have been submitting or have had active review of their monthly QC reports by the HPTN NL.:

| | | |
|----------|----------|------|
| UZ-UCSF | Lilongwe | HNSC |
| RIHES | NARI | IP |
| Guangxi | YRG Care | |
| Xinjiang | Blantyre | |

NL updates

The NL is working on the incidence testing for both HPTN 043 and the domestic trials.

Travel Updates

Paul will be travelling to Uganda and Tanzania in April.

Paul and Estelle are planning a visit to NARI and YRG Care in June.

Implementations Issues and Problems Summary April 2010

052

All sites listed above are operating under Version 3.0 of the protocol. As of April 8, 2010, the study met its enrollment target of 1750 couples. Sites will continue to enroll couples who are in the screening pipeline. SCHARP will officially announce when enrollment has ended, along with the final total N of the study.

058

Study drug cannot be shipped to the new site in Nanning until the site is officially approved within China for study drug dispensation. The study drug supply for this first shipment has an August 2010 expiry date.

061

To improve the number of index referrals, the study team has decided to expand "index" status to all participants who test HIV negative at enrollment. The LoA to allow this change was approved on April 7, 2010. Analysis of the focus group data is taking place at this time, with the first two rounds of coding and review completed. The qualitative team has finalized the questionnaire for the qualitative interviews and some sites have begun conducting their interviews.

062

Accrual will be dependent on one site and its ability to identify acutely infected individuals within the lifespan of CHAVI 001.

063

The Zambian MOH did not approve the protocol because of the ban on sample exportation. The decision has been appealed and the site is in close communication with the MOH; however, the study-specific training has been postponed until the MOH provides some indication that the study will be able to be approved.

The Brazilian central IRB (CONEP) took longer than expected to approve the study. The original submission was on 04 May 2009. The approval is dated for 16 December 2009, although the site was not notified of the approval until 03 February 2010. The site is now waiting to receive approval/sign-off from their MOH so that state department clearance can be issued. It is not clear how long this process will take. The site has confirmed that MOH approval is a formality once CONEP and local IRB approval are received which have both been done. However, this approval must be in place in order to receive state department clearance.

064

Accrual and retention are both being monitored very closely at all sites to ensure study targets are met.

065 At this time, study preparedness and implementation is proceeding smoothly.

Report for HPTN Study Operations Group

HPTN 027

A PHASE I STUDY TO EVALUATE THE SAFETY AND IMMUNOGENICITY OF ALVAC-HIV vCP1521 IN INFANTS BORN TO HIV-1 INFECTED WOMEN IN UGANDA

Based on available data through: 13 April 2010

Participating Study Site:

Makerere University-Johns Hopkins University Research Collaboration/Mulago Hospital
Kampala, Uganda

Study Implementation Status:

24-month study follow-up is complete. Site has de-registered.

CRF Database was locked from any further submissions on 29 October.

Study samples are en route from the site to JHU for analysis. Some of the lab data assay data has been received from the Richmond Lab.

Accrual Status:

60 of 60 have been enrolled. Accrual is complete.

Status of Intervention Delivery:

N/A

Retention Status:

N/A

Report for HPTN Study Operations Group

HPTN 046

A phase III trial to determine the efficacy and safety of an extended regimen of nevirapine in infants born to HIV-infected women to prevent vertical transmission during breastfeeding

Based on available data through: 13 April 2010

Participating Study Sites:

CAPRISA Umlazi; Durban, South Africa
Muhimbili Hospital; Dar es Salaam, Tanzania
Mulago Hospital; Kampala, Uganda
Chitungwiza Clinics; Chitungwiza, Zimbabwe

Study Implementation Status:

Enrollment closed on 21 January. All infants have been randomized. The last infant will complete 6 month follow-up and complete study product dosing in July.

Accrual Status:

The study enrolled 1674 mother-infant pairs [1670 infants in all].

Status of Intervention Delivery:

Retention Status:

There have been no retention issues identified at this time.

Implementation Issues and Problems:

No issues at this time.

Report for HPTN Study Operations Group

HPTN 052

A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 In Serodiscordant Couples *Based on available data through: 2 April 2010*

Participating Study Sites:

Gaborone, Botswana
Porto Alegre and Rio de Janeiro, Brazil
Chennai, India
Pune, India
Blantyre, Malawi
Lilongwe, Malawi
Johannesburg, South Africa
Soweto, South Africa
Chiang Mai, Thailand
Harare, Zimbabwe
Kisumu, Kenya

Study Implementation Status:

All sites listed above are operating under Version 3.0 of the protocol. As of April 8, 2010, the study met its enrollment target of 1750 couples. Sites will continue to enroll couples who are in the screening pipeline. SCHARP will officially announce when enrollment has ended, along with the final total N of the study.

Accrual Status:

Below is site-reported screening and enrollment data; refer also to the SCHARP enrollment summary.

| HPTN 052 Cumulative Screening and Enrollment Data | | | | | | | | | | | | | | | |
|--|-----------|-----------|-----------|-----------|------------------|---------------|---------------|-----------|-----------|-----------|-----------|-----------|-----------|-------------|---------|
| Week Ending: 31 March 2010 | | | | | | | | | | | | | | | |
| | Lilongwe | RIHES | NARI | Blantyre | Brazil - FIOCRUZ | Brazil - HGNI | Brazil - HNSC | YRG CARE | Zimbabwe | WITS SA | Botswana | Soweto | Kenya | Individuals | Couples |
| Date First Screened | 04-Apr-05 | 13-Jun-05 | 22-Jun-05 | 16-Aug-05 | 13-Sep-05 | 03-Oct-05 | 04-Jan-06 | 08-Nov-05 | 07-Dec-05 | 07-Apr-08 | 11-Mar-09 | 21-May-09 | 21-Oct-09 | | |
| Date First Enrolled | 12-Apr-05 | 24-Jun-05 | 01-Jul-05 | 25-Aug-05 | 14-Sep-05 | 13-Oct-05 | 30-Jan-06 | 10-Nov-05 | 09-Jan-06 | 20-May-08 | 16-Apr-09 | 11-Jun-09 | 03-Nov-09 | | |
| # Screened* | 1494 | 550 | 712 | 1942 | 386 | 366 | 274 | 1106 | 2320 | 188 | 478 | 425 | 496 | 10775 | n/a |
| # Enrolled - Individuals | 500 | 214 | 348 | 462 | 208 | 152 | 178 | 500 | 462 | 88 | 148 | 96 | 104 | 3474 | n/a |
| # Enrolled - Couples | 250 | 107 | 174 | 231 | 104 | 76 | 89 | 250 | 231 | 44 | 74 | 48 | 52 | n/a | 1737 |
| Eligible | 508 | 209 | 390 | 456 | 210 | 152 | 178 | 600 | 512 | 82 | 150 | 106 | 110 | 3685 | n/a |
| Ineligible | 962 | 336 | 312 | 1430 | 174 | 208 | 96 | 498 | 1788 | 94 | 326 | 312 | 292 | 6844 | 3422 |
| Eligibility Unknown | 24 | 5 | 10 | 56 | 2 | 6 | 0 | 8 | 20 | 12 | 2 | 7 | 94 | 246 | n/a |
| Individuals # Screened/Individuals # Enrolled | 3.0 | 2.6 | 2.0 | 4.2 | 1.9 | 2.4 | 1.5 | 2.2 | 5.0 | 2.1 | 3.2 | 4.4 | 4.8 | 3.1 | n/a |

- *One participant may have multiple screening attempts.
- ** Fenway and HSE have been phased out of participation in HPTN 052 and will no longer screen and enroll participants.
- ***Total enrollment numbers in above chart account for couples enrolled at both Fenway and HSE, though not shown. As such, the total number of couples is always going to be 7 more than what each individual site enrolled adds up to – this is explained in the table below.

Termination/Transfer Status of Couples at Fenway and HSE:

| | HSE | Fenway |
|--|--------------|---------------|
| # Couples enrolled during run-in period | 5 | 2 |
| # Terminated couples | 2 | 2 |
| # Transferred couples to IPEC | 3 | N/A |
| Date of last terminated/transferred couple | 26 July 2007 | 9 May 2007 |

Retention Status:

Refer to the SCHARP "Couples Status" retention summary available on Atlas.

Implementation Issues and Problems:

Refer to the Network Laboratory report for any issues and problems related to the clinical site laboratories.

Report for HPTN Study Operations Group

HPTN 057

A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and their Infants

Based on available data through: 9 April 2010

Participating Study Sites:

Malawi - Queen Elizabeth Central Hospital, Malawi College of Medicine-JHU Research Project, Blantyre (QECH)

Brazil - Federal University of Minas Gerais, Belo Horizonte (UFMG)

- Irmandade Santa Casa de Misericordia de Porto Alegre, Porto Alegre (Santa Casa)
- Hospital dos Servidores do Estado – Serviço de Doenças Infecciosas, Rio de Janeiro (HSD)
- Hospital Nossa Senhora da Conceicao Serviço de Infectologia, Porto Alegre (Conceicao)

Study Implementation Status: Enrollment into Cohorts 1, 2 and 3 was completed on Sept 16, 2008. A total of 81 evaluable mother/infant pairs were enrolled. Follow-up of participants in Cohorts 1, 2, and 3 is complete.

The protocol was amended to add a fourth cohort looking at a maternal dose during labor and daily infant dosing for 1 week. The target number of mother/infant pairs for enrollment into Cohort 4 is 30. It is anticipated that approximately half of the pairs will be enrolled in Blantyre and the other half will be enrolled across the four Brazil sites.

The Blantyre Site opened for accrual to Cohort 4 on 4 April 2010. Study Drug has been shipped to the Blantyre site and is expected to arrive next week. The site will avoid screening women that are late in gestation to avoid a delivery when drug has not yet arrived.

The Brazil sites are expected to have all approvals in place and open for accrual in May 2010.

Accrual Status:

Below is the site reported enrollment summary for Cohorts 1, 2 and 3; refer also to the SHARP enrollment summary.

| Site | # Evaluable Mother/Infant Pairs Enrolled | | | |
|---|--|----------|----------|----------|
| | Cohort 1 | Cohort 2 | Cohort 3 | Cohort 4 |
| Queen Elizabeth Central Hospital, Blantyre Malawi | 24 | 16 | 15 | |
| Santa Casa, Porto Alegre Brazil | 3 | 4 | 4 | |
| University of Minas Gerais, Belo Horizonte Brazil | 3 | 1 | 2 | |
| Conceicao, Porto Alegre Brazil | - | - | 4 | |
| Hospital do Servidores, Rio de Janeiro Brazil | - | - | 5 | |
| Total | 30 | 21 | 30 | |

Status of Intervention Delivery:

There were no reported significant problems with the dispensing of tenofovir to the mothers or infants in Cohorts 1 – 3.

Retention Status:

Two mother/infant pairs for Cohorts 1 – 3 have been lost to follow-up.

Implementation Issues and Problems:

Report for HPTN Study Operations Group

HPTN 058

A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection and death among opiate dependent injectors

Based on data available through 9 April 2010

Participating Study Sites:

- Xinjiang Uighur Autonomous Region, Centers for Disease Control and Prevention, Xinjiang, China
- Heng County, Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, Guangxi, China
- Guangxi Zhuang Autonomous Region, Centers for Disease Control and Prevention, Nanning, Guangxi, China
- Research Institute for Health Sciences, Chiang Mai, Thailand

Study Implementation Status:

Enrollment in Chiang Mai was capped at 202 participants. Xinjiang has enrolled 241 participants. Heng County, Guangxi has enrolled 226 participants. The clinic in Urumqi remains relocated to their proposed satellite site due to orders from the Chinese authorities. Anticipated completion date of the renovations to the main clinic is June 2010. DAIDS issued an approval for this temporary relocation. The ban on international communications has been lifted.

The Nanning site (also in Guangxi Province) has been approved by NIH and the local authorities but site activation will not occur until study drug is on site. Adding a site in Vietnam still remains a possibility. The team held a Site Selection Committee on 3 February 2010. The team discussed approving the site for development predicated on the site being able to meet certain deadlines for obtaining all approvals. This request was submitted to the EC for discussion on the 3 March call. A budget must be received from the Site.

Marek Chawarski has circulated a new draft of the Counseling Manual for review among team members. The team has continued regular conference calls with the counselors to address any questions they have about this component of the study.

The team continues to work on recruiting among a higher risk cohort and improving retention. To improve retention, the group is researching the feasibility of completing follow-up visits among participants who are incarcerated. This will require a protocol change and OHRP approval of the plan.

Discussions are under way to formulate a plan to allow Suboxone compassionate use for participants who have completed 058 follow-up.

Accrual Status:

| | Chiang Mai | Guangxi | Xinjiang |
|-------------------------------|-------------------|----------------|-----------------|
| Date First Screened | 11-Apr-07 | 19-Dec-08 | 19-Dec-08 |
| Date First Enrolled | 30-May-07 | 24-Dec-08 | 21-Dec-08 |
| # Individuals Screened | 281 | 470 | 447 |
| # Individuals Enrolled | 202 | 226 | 241 |

Status of Intervention Delivery:

Study drug has been generally well tolerated.

Retention Status:

| All Sites | |
|-----------|-----|
| Week 26 | 87% |
| Week 52 | 79% |
| Week 78 | 82% |
| Week 104 | 82% |
| Week 130 | 80% |

Implementation Issues and Problems:

Study drug cannot be shipped to the new site in Nanning until the site is officially approved within China for study drug dispensation. The study drug supply for this first shipment has an August 2010 expiry date.

Report for HPTN Study Operations Group

HPTN 061

Feasibility study of a community-level, multi-component intervention for Black men who have sex with men in preparation for a community-level randomized trial to test the efficacy of the intervention in reducing HIV incidence among Black men who have sex with men

Based on data available through: 11 April 2010

Participating Study Sites:

- Ponce de Leon Center CRS (site 5802) and Hope Clinic CRS (site 31440) in Atlanta and Decatur, Georgia, respectively
- San Francisco Vaccine and Prevention CRS in San Francisco, California (site 30305)
- New York Blood Center (NYBC)/Union Square CRS (site 31605) and Harlem Prevention Center CRS (site 30276) in New York City, New York
- University of California at Los Angeles (UCLA) Vine Street CRS (site 31607) in Los Angeles, California
- The Fenway Institute CRS (site 31602) in Boston, Massachusetts
- George Washington University CRS (site 31608) in Washington, D.C.

Study Implementation Status:

All sites for the HPTN 061 protocol are enrolling and following participants.

| Site | Date of Activation | Date of First Enrollment |
|--|--------------------|--------------------------|
| The Fenway Institute | 06 July 2009 | 17 July 2009 |
| George Washington University | 20 July 2009 | 28 July 2009 |
| San Francisco Vaccine and Prevention CRS | 11 August 2009 | 13 August 2009 |
| New York Blood Center | 24 August 2009 | 01 October 2009 |
| Hope Clinic CRS | 04 September 2009 | 16 September 2009 |
| UCLA | 25 September 2009 | 29 September 2009 |
| Ponce de Leon CRS | 09 October 2009 | N/A |
| Harlem Prevention Center | 05 January 2010 | 08 January 2010 |

Accrual Status (participants enrolled at each site) as of 11 April 2010:

| Fenway | GWU | Emory :Ponce +Hope | San Fran | UCLA | NYBC | Harlem | TOTAL |
|--------|-----|--------------------|----------|------|------|--------|-------|
| 126 | 122 | 131 | 135 | 142 | 70 | 70 | 796 |

Status of Intervention Delivery:

To improve the number of index referrals, the study team has decided to expand "index" status to all participants who test HIV negative at enrollment. The LoA to allow this change

was approved on April 7, 2010. Analysis of the focus group data is taking place at this time, with the first two rounds of coding and review completed. The qualitative team has finalized the questionnaire for the qualitative interviews and some sites have begun conducting their interviews.

Retention Status:

The early-activating sites are beginning to conduct six month visits. So far retention has been good with only a few participants not returning for their visits, but the site teams are confident that they will be able to locate those people and get them to come back.

Implementation Issues and Problems:

See above in "Status of Intervention Delivery"

Report for HPTN Study Operations Group

HPTN 062

Feasibility and Acceptability Study of an Individual-Level Behavioral Intervention for Individuals with Acute and Early HIV-Infection

Based on data available through: 08 April 2010

Participating Study Sites:

- University of North Carolina Project, Kamuzu Central Hospital, Lilongwe, Malawi

Study Implementation Status:

Version 2.0 of the protocol, dated 10 September 2009, was approved by DAIDS and distributed to the sites on 16 September 2009. All IRB approvals have been received.

Lilongwe site was activated on 24 February 2010. To date, there have been no acutely infected individuals identified.

A Clarification Memo is being developed to clarify when "provider notification" will be offered at the site.

Accrual Status (completed at all sites):

No enrollment yet.

Status of Intervention Delivery:

No enrollment yet.

Retention Status:

N/A

Implementation Issues and Problems:

Accrual will be dependent on one site and its ability to identify acutely infected individuals within the lifespan of CHAVI 001.

Report for HPTN Study Operations Group

HPTN 063

Preparing for International Prevention Trials Involving HIV-Infected Individuals in Care Settings

Based on data available through: 05 April 2010

Participating Study Sites:

- Matero Clinic CRS; Lusaka, Zambia
- Chiang Mai University AIDS Prevention CRS; Chiang Mai, Thailand
- Instituto de Pesquisa Clinica Evandro Chagas (IPEC) CRS; Rio de Janeiro, Brazil

Study Implementation Status:

Version 1.0 of the protocol was approved on 15 September 2008 and distributed to sites on the same day. The English and translated versions of the CRFs and ACASI scripts are final (in Portuguese, Thai, Bemba, and Nyanja). The Thai audio recordings are final. The Portuguese is expected to be final in mid April. Bemba and Nyanja audio recordings are delayed due to non-approval of the protocol from the local Ministry of Health.

The qualitative assessments for HPTN 063 were final as of 26 March 2009 and have been translated by the sites.

The Thai site was activated on 26 March 2010 and enrolled their first participant on 01 April 2010.

The Brazil site has received local and central IRB (CONEP) approvals and is currently awaiting state department clearance.

The Zambia site received local and UAB IRB approvals but received a non-approval letter from the Ministry of Health (MOH) on 13 January 2010, due to a current ban on sample exportation. They have appealed the decision and are awaiting feedback.

Site activation activities are continuing at the Brazil and Zambia sites. The site training schedule is as follows: Thailand (25-29 January, 2010 - **Completed**), Zambia (8-12 March, 2010 - **Postponed**), and Brazil (1-5 March, 2010 - **Completed**).

Accrual Status:

Below is site-reported screening and enrollment data; refer also to the SCHARP enrollment summary.

| Site | Date of First Screening | Date of First Enrollment | Total No. Screened | No. Report No Unprotected Sex | No. Not Receiving Care | Total No. Enrolled |
|------------------------------------|-------------------------|--------------------------|--------------------|-------------------------------|------------------------|--------------------|
| Brazil: Rio de Janeiro (IPEC CRS) | | | | | | |
| Women | | | | | | |
| Heterosexual Men | | | | | | |
| MSM | | | | | | |
| Thailand: Chiang Mai | 01-Apr-10 | 01-Apr-10 | | | | |
| Women | | | 1 | 0 | 0 | 1 |
| Heterosexual Men | | | | | | |
| MSM | | | | | | |
| Zambia: Lusaka (Metero Clinic CRS) | | | | | | |
| Women | | | | | | |
| Heterosexual Men | | | | | | |
| TOTAL | NA | NA | 1 | 0 | 0 | 1 |

Retention Status:

Refer to the SCHARP retention summary.

Implementation Issues and Problems:

The Zambian MOH did not approve the protocol because of the ban on sample exportation. The decision has been appealed and the site is in close communication with the MOH; however, the study-specific training has been postponed until the MOH provides some indication that the study will be able to be approved.

The Brazilian central IRB (CONEP) took longer than expected to approve the study. The original submission was on 04 May 2009. The approval is dated for 16 December 2009, although the site was not notified of the approval until 03 February 2010. The site is now waiting to receive approval/sign-off from their MOH so that state department clearance can be issued. It is not clear how long this process will take. The site has confirmed that MOH approval is a formality once CONEP and local IRB approval are received which have both been done. However, this approval must be in place in order to receive state department clearance.

Report for HPTN Study Operations Group
HPTN 064
Women's Seroprevalence Study (ISIS)
Based on data available through: 07 April 10

Participating Study Sites:

- Emory University, Atlanta, Georgia (Ponce de Leon Center CRS and Hope Clinic CRS)
- Johns Hopkins Adult AIDS CRS, Baltimore, Maryland
- University of North Carolina-Chapel Hill, North Carolina (UNC AIDS CRS and Wake County Health and Human Services CRS)
- Columbia University, New York, New York (Bronx-Lebanon Hospital Center CRS and Harlem Prevention Center CRS)
- New Jersey Medical School Adult Clinical Trials Center, Newark, New Jersey
- George Washington University School of Public Health and Health Services, Washington D.C.

Study Implementation Status:

All HPTN 064 study sites have been activated and screening and enrollment is well underway.

The Bronx-Lebanon Hospital Center (BLHC) and the UNC AIDS CRS (both Durham and Wake counties) have both successfully enrolled a total of 210 women. GWU has successfully begun enrolling an additional 10 women for a total of 210 women. All other sites have met their half-way points for recruitment.

All qualitative sites have successfully completed all qualitative interviews and are actively recruiting for focus groups.

On February 22, 2010, the SMC conducted its initial review of HPTN 064 and advised that the HPTN 064 Protocol Team explore options for increasing person-years within the limitations of the current protocol (e.g., extending the length of follow-up for participants from 6 to 12 months).

In response, the HPTN 064 Protocol Team has outlined a set of guidelines that maximize participant follow-up while remaining within current timelines and constraints of the HPTN 064 Protocol, Version 1.0 dated July 9, 2008. On April 7, 2010, the HPTN EC approved the extension of follow-up. Sites are currently taking the steps necessary to implement these guidelines.

Accrual Status:

Please see SCHARP Enrollment Report.

Status of Intervention Delivery:

N/A

Retention Status:

Please see SCHARP Retention Report.

Implementation Issues and Problems:

Accrual and retention are both being monitored very closely at all sites to ensure study targets are met.

Report for HPTN Study Operations Group

HPTN 065

TLC-Plus: A Study to Evaluate the Feasibility of an Enhanced Test, Link to Care, Plus Treat Approach for HIV Prevention in the United States

Based on available data through: 12 April 2010

Participating Study Sites:

HPTN 065 includes two intervention communities (Washington, D.C. and the Bronx, New York) and four comparator communities (Miami, Florida; Philadelphia, Pennsylvania; Chicago, Illinois; and Houston, Texas). There will be a total of 80 sites (40 test sites and 40 care sites) located in Washington, D.C. and the Bronx, New York that will actively participate in the study. In each intervention location, there will be 20 test sites and 20 care sites.

Study Implementation Status:

The protocol received final approval for V1.0 on March 16, 2010. The protocol has been submitted to a central IRB for review. The study team is now in the process of site selection for the 40 test sites and 40 care sites that will participate in the study. To date, 14 LoIs (Letters of Intent) in DC and 15 LoIs in the Bronx have been signed. The LoI indicates a site's intention to participate in the study and be randomized for the interventions.

Expansion of HIV testing:

- Creative agencies in DC and the Bronx are working on the social mobilization efforts, with the goal of implementation in June 2010.
- Hospitals in DC and the Bronx have been approached to participate in the study. Conference calls continue to work out the details of their participation.

Linkage-to-Care (L2C) and Viral Load Suppression (VLS):

- HIV test and care sites are being selected to participate in these two study components.
- Staff training for these study components are scheduled for the following dates in May: 5-6 (DC), 13-14 (Bronx), 18-19 (DC), and 26-27 (Bronx). Including a pilot training scheduled for April 22 in DC, a total of 17 trainings for these two study components will be conducted.
- The L2C and VLS study components are targeted to begin in June 2010.

Prevention for Positives (PfP):

- The study team is working to update the CARE+ program so that it can be implemented in Aug-Sept 2010.

Patient and Provider Surveys:

- The patient and provider surveys are undergoing final development and pilot testing.

Accrual Status: N/A

Retention Status: N/A

Implementation Issues and Problems:

At this time, study preparedness and implementation is proceeding smoothly.

Appendix: HPTN Protocols and INDs

| Protocol # | | IND | IND Sponsor | Study Status |
|-------------------|--|--------------|--------------------|---------------------|
| HPTN 027 | A Phase I Study to Evaluate the Safety and Immunogenicity of ALVAC-HIV vCP1521 in Infants Born to HIV-1 Infected Women in Uganda | BB-IND 12023 | DAIDS | Closed to Accrual |
| HPTN 046 | Phase III Trial to Determine the Efficacy and Safety of an Extended Regimen of Nevirapine in Infants Born to HIV Infected Women to Prevent Vertical HIV Transmission During Breastfeeding | 72,592 | DAIDS | Closed to Accrual |
| HPTN 052 | A Randomized Trial to Evaluate the Effectiveness of Antiretroviral Therapy Plus HIV Primary Care versus HIV Primary Care Alone to Prevent the Sexual Transmission of HIV-1 in Serodiscordant Couples | 68,535 | DAIDS | Enrolling |
| HPTN 057 | A Phase I Open Label Trial of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-1 Infected Pregnant Women and their Infants | 72,531 | DAIDS | Open to Accrual |
| HPTN 058 | A Phase III randomized controlled trial to evaluate the efficacy of drug treatment in prevention of HIV infection and death among opiate dependent injectors | 73,797 | DAIDS | Enrolling |